

PBM-2015-04

SEPTEMBER 2, 2015

ITEM: REFRESH® Lacri-Lube®, REFRESH P.M.®, FML® (fluorometholone ophthalmic ointment) 0.1%, and Blephamide® (Sulfacetamide Sodium And Prednisolone Acetate Ophthalmic Ointment, USP) 10%/0.2%: Recall for Particulate Matter

SPECIFIC INCIDENT(S): Allergan is conducting a voluntary recall for specific lots of the REFRESH® Lacri-Lube®, REFRESH P.M.®, FML® (fluorometholone ophthalmic ointment) 0.1%, Blephamide® (sulfacetamide sodium and prednisolone acetate ophthalmic ointment, USP) 10%/0.2% due to small black particulate matter that may cause eye pain, eye swelling, ocular discomfort or eye irritation.

GENERAL INFORMATION:

- Reports document complaints of a small black particle (which is part of the cap) at the time of use potentially introduced into the product by the action of unscrewing the cap from the aluminum tube.
- Allergan has received adverse events reports that include: foreign body in eye (12), eye irritation (2), ocular discomfort (2), product contamination (2), superficial injury of eye (2), eye pain (1), eye swelling (1) and blurred vision (1).
- Affected products and lots are included below:

NDC	DESCRIPTION	LOT NUMBER, EXPIRATION DATE
0023-0312-04	REFRESH® Lacri-Lube® 3.5 g	84746, Apr-17; 84987, May-17; 85087, May-17; 85359, Jun-17; 85721, Jul-17; 86045, Aug-17; 86406, Sep-17; 86594, Oct-17; 87021, Nov-17
0023-0312-07	REFRESH® Lacri-Lube® 7g	86470, Sep-17; 86829, Oct-17; 87105, Nov-17
0023-0240-04	REFRESH P.M.® 3.5 g	85165, May-17; 85228, May-17; 85244, Jun-17; 85351, Jun-17; 85374, Jun-17; 85397, Jun-17; 85561, Jul-17; 85676, Jul-17; 85694, Jul-17; 85834, Aug-17; 85977, Aug-17; 85985, Aug-17; 86073, Aug-17; 85599, Sep-17; 86290, Sep-17; 86325, Sep-17; 86411, Sep-17; 86427, Sep-17; 86506, Sep-17; 86515, Sep-17; 86517, Sep-17; 86746, Oct-17; 86792, Oct-17; 86789, Oct-17; 86809, Oct-17; 86822, Oct-17; 86822A, Oct-17; 86932, Nov-17; 87100, Nov-17; 87068, Nov-17; 87156, Dec-17; 87261, Dec-17; 87493, Jan-18; 87494, Feb-18; 87731, Feb-18
0023-0240-04	REFRESH P.M.® 3.5 g (Professional Sample Pack)	85165, May-17; 86789, Oct-17

0023-0316-04	FML® (fluorometholone ophthalmic ointment) 0.1%, 3.5 g	86258, Sep-17; 87189, Dec-17; 87514, Feb-18
0023-0313-04	Blephamide® (sulfacetamide sodium and prednisolone acetate ophthalmic ointment, USP) 10%/0.2%, 3.5 g	86430, Sep-17; 87806, Feb-18; 88147, Mar-18

- This alert is an extension of the product sequestration actions in **Product Recall Office Log # 9972** (available at: <http://vaww.recalls.ncps.med.va.gov/WebRecalls/Recalls.html>).
- Providers should continue to report any adverse reactions with the use of REFRESH® Lacri-Lube®, REFRESH P.M.®, FML® (fluorometholone ophthalmic ointment) 0.1%, Blephamide® (sulfacetamide sodium and prednisolone acetate ophthalmic ointment, USP) 10%/0.2% product(s) by entering the information into CPRS' Allergies/ Adverse Reactions field and/or via local reporting mechanisms. Adverse events should also be reported, as appropriate, to the VA ADERS program and FDA MedWatch (1-800-FDA-1088, fax 1-800- FDA-0178, online at <https://www.accessdata.fda.gov/scripts/medwatch/medwatch-online.htm>, or by mail).

ACTIONS:

PROVIDER NOTIFICATION:

- **Facility Director** (or physician designee): Forward this document to the Facility Chief of Staff (COS).
- **Facility COS** (and Chief Nurse Executives): Forward this document to all appropriate providers who prescribe this agent (e.g., **primary care providers, eye care specialists, and pharmacy staff, including contract providers**, etc.). In addition, forward to the Associate Chief of Staff (ACOS) for Research and Development (R&D). Forward to other VA employees as deemed appropriate.
- **ACOS for R&D**: Forward this document to Principal Investigators (PIs) who have authority to practice at the facility and to your respective Institutional Review Board (IRB).

PATIENT NOTIFICATION:

- **Chief of Pharmacy**: Within 10 business days of issue (due 09/16/2015):
 - Determine whether the affected product(s) was dispensed to any patient(s) for home administration.
 - If an affected lot(s) was dispensed to a patient(s) for home administration, then:
 - Identify the patient(s).
 - Contact the patient(s) who may have received the affected product(s) for home administration by letter (or other means).
 - A sample letter can be found at: <https://vaww.cmopnational.va.gov/cmop/PBM/Other%20Documents%20and%20Resources/ASA%20Recall%20Patient%20Letter%20Template.doc>.
 - This template can be altered according to site-specific needs.
 - Provide patient(s) in possession of the recalled product with

instructions on the following:

- How to return the product being recalled to the pharmacy.
 - How to obtain a new supply of product.
 - Patients should not continue to take the product until they obtain replacement product.
 - When the correct product is received, patients should begin using the new product and return the recalled supply as instructed.
- Communicate to PBM/VAMedSAFE that all patient notification actions have been completed via the VHA Alerts and Recalls Website:
<http://vaww.recalls.ncps.med.va.gov/WebRecalls/Recalls.html>.

SOURCE: FDA

REFERENCE(S):

1. FDA Recall – Firm Press Release: Allergan Issues Voluntary Nationwide Recall In The U.S. Of Specific Lots Of REFRESH® Lacri-Lube®, REFRESH P.M.®, FML® (fluorometholone ophthalmic ointment) 0.1%, and Blephamide® (Sulfacetamide Sodium And Prednisolone Acetate Ophthalmic Ointment, USP) 10%/0.2% For Particulate Matter.
http://www.fda.gov/Safety/Recalls/ucm459485.htm?source=govdelivery&utm_medium=email&utm_source=govdelivery . (Accessed 08/27/2015)

ATTACHMENT(S): None.

CONTACTS: Pharmacy Benefits Management Services (PBM) at (708)786-7862.